

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

UNITED STATES OF AMERICA,

Plaintiff,

vs.

DEVENKUMAR. C. PATEL,
a/k/a DEVEN PATEL,

Defendant.

Civil Action
No.

Criminal Action
No 2:13-CR-20481-VAR-MKM
Hon. Victoria Roberts

**(CORRECTED) BRIEF IN SUPPORT OF MOTION
FOR POST-CONVICTION RELIEF**

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STATEMENT OF ISSUES PRESENTED

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- II. IS THE DEFENDANT EXEMPT FROM THE TRADITIONAL GOOD CAUSE AND PREJUDICE ASSOCIATED WITH 2255 PETITIONS WHERE THE ISSUE COULD NOT HAVE BEEN RAISED IN HIS ORIGINAL APPEAL?
- III. WAS THE DEFENDANT'S PLEA FATALLY DEFECTIVE BECAUSE THERE WAS NO FACTUAL BASIS FOR THE FINDING OF THE REQUISITE SCIENTER FOR THE OFFENSES TO WHICH HE PLED?
- IV. WAS THE DEFENDANT DENIED EFFECTIVE ASSISTANCE OF COUNSEL WHEN COUNSEL'S ERRONEOUS LEGAL ADVICE AS TO SCIENTER INDUCED HIM TO PLEAD GUILTY FOR CONDUCT WHICH IS NOT IN FACT CRIMINAL AND RENDERED HIS PLEA UNKNOWNING AND INVOLUNTARY?

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STATEMENT OF FACTS

On June 25, 2013, Mr. Patel was charged in an Information with unlawful distribution of a controlled substance, pursuant to 21 U.S.C.A. § 842(a), and healthcare fraud, pursuant to 18 U.S.C.A. §1347.

He entered into a written Rule 11 plea agreement with the United States Attorney on September 6, 2013. The agreement purported to recite the elements of the crimes of unlawful distribution of a controlled substance and healthcare fraud. The agreement also contained a narrative of fact which purported to be “a sufficient and accurate basis” to support Mr. Patel’s guilty plea to unlawful distribution of a controlled substance and healthcare fraud. Mr. Patel entered into this agreement on the advice of counsel. The agreement is signed by both Mr. Patel and the attorney who was representing Mr. Patel at that time.

On June 13, 2013, Mr. Patel tendered a plea of guilty to unlawful distribution of a controlled substance, pursuant to 21 U.S.C.A. § 842(a), and healthcare fraud, pursuant to 18 U.S.C.A. §1347, as provided by the Rule 11 agreement. In his plea soliloquy, Mr. Patel admitted that he was negligent in his supervision of the pharmacists in his employ and that he should have known that on occasion they were dispensing a controlled substance without a valid prescription. He made no admission that he had actual knowledge of the unlawful conduct. The Court accepted Mr. Patel’s pleas and found him guilty of both offenses.

This Court sentenced Mr. Patel to a term of 17 months imprisonment and imposed other terms and conditions. He was directed to report to the Bureau of Prisons on August 25th, 2016. On Mr. Patel's motion, the reporting date was deferred to November 18, 2016.

ARGUMENT

I. THE MATTER IS PROPERLY BEFORE THE COURT

This petition is brought under 28 U.S.C.A. § 2255 challenging the validity of Mr. Patel's plea based conviction to one count of unlawful distribution of a controlled substance, pursuant to 21 U.S.C.A. § 842(a), and one count of, healthcare fraud, pursuant to 18 U.S.C.A. §1347. Mr. Patel tendered a guilty plea but the plea was tendered unknowingly and involuntarily and the factual basis was inadequate to support a conviction on either count. Mr. Patel originally filed a Notice of Appeal but in light of the ambiguous state of the law as to the issues which survive a plea waiver and after more fully recognizing that much of his claims of error rest on matters not fully developed on the record, he has voluntarily dismissed his appeal to the Sixth Circuit in favor of this instant Petition for Post-Conviction Relief under 28 U.S.C.A. § 2255.

28 U.S.C.A. § 2255 provides in pertinent part:

A prisoner in custody under sentence of a court established by Act of Congress claiming the right to be released upon the ground that the sentence was imposed in violation of the Constitution or laws of the United States, or that the court was without jurisdiction to impose such sentence, or that the sentence was in excess of the maximum authorized by law, or is otherwise subject to collateral attack, may move the court which imposed the sentence to vacate, set aside or correct the sentence.

Unless the motion and the files and records of the case conclusively show that the prisoner is entitled to no relief, the court shall cause notice thereof to be served upon the United States attorney, grant a prompt hearing thereon, determine the issues and make findings of fact and conclusions of law with respect thereto. If the court finds that the judgment was rendered without jurisdiction, or that the sentence imposed was not authorized by law or otherwise open to collateral attack, or that there has been such a denial or infringement of the constitutional rights of the prisoner as to render the judgment vulnerable to collateral attack, the court shall vacate and set the judgment aside and shall discharge the prisoner or resentence him or grant a new trial or correct the sentence as may appear appropriate.

An action under 28 U.S.C.A. § 2255 is the preferred method for challenging a conviction based on facts not contained in the record. The Sixth Circuit has made it clear that where factual development of an issue is required, the appeal of right is not the proper vehicle to raise the claim. See, e.g., *United States v. Tucker*, 90 F.3d 1135, 1143 (6th Cir.1996); *United States v. Neuhausser*, 241 F.3d 460 (6th Cir. 2001); *United States v. Delgado*, 350 F.3d 520, 527 (6th Cir. 2003).

A motion for post-conviction relief under 28 U.S.C.A. § 2255 has been utilized in other cases as a vehicle for challenging the validity of a guilty plea. As our

Supreme Court recognized in *Fontaine v. United States*, 411 U.S. 213, 93 S.Ct. 1461 (1973):

Petitioner's motion for relief under s 2255 sets out detailed factual allegations regarding alleged circumstances occurring after his arrest and before his appearance in court. Those allegations describe physical abuse and illness from a recent gunshot wound that required hospitalization which was documented by records tendered in support of his petition. The records also showed that a month following the plea he was again hospitalized for heroin addiction, for aggravation of the earlier gunshot wound and for other severe illnesses. Petitioner further alleges that prolonged interrogation continued during the period preceding his plea. All of this, he claims, coerced his confession, his waiver of counsel, and the uncounseled plea of guilty. It is elementary that a coerced plea is open to collateral attack. *Machibroda v. United States*, supra, at 493, 82 S.Ct., at 513. See also *Waley v. Johnston*, 316 U.S. 101, 62 S.Ct. 964, 86 L.Ed. 1302; *Walker v. Johnston*, 312 U.S. 275, 61 S.Ct. 574, 85 L.Ed. 830; *Diamond v. United States*, 9 Cir., 432 F.2d 35, 39; *Crow v. United States*, 10 Cir., 397 F.2d 284, 285--286. It is equally clear that s 2255 calls for a hearing on such allegations unless 'the motion and the files and records of the case conclusively show that the prisoner is entitled to no relief'

Id at 214.

In opposing Mr. Fontaine's petition, the Government argued that the Defendant's on the record statements concerning the voluntariness of the plea should be treated as dispositive. The United States Supreme Court rejected the notion. The Court found that such statements were relevant, but not dispositive. The Court wrote:

We need not take issue with the Government's generalization that when a defendant expressly represents in open court, without counsel, that his plea is voluntary and that he waived counsel voluntarily, he 'may not ordinarily' repudiate his statements to the sentencing judge. The objective of Fed.Rule Crim.Proc. 11, of course, is to flush out and

resolve all such issues, but like any procedural mechanism, its exercise is neither always perfect nor uniformly invulnerable to subsequent challenge calling for an opportunity to prove the allegations.

See also *Borrie v. Malkowski*, 134 F.3d 370 (6th Cir. 1998) (2254 proceeding). As Judge Easterbrook has noted, “. . . the rules of procedure should be designed to induce litigants to present their contentions to the right tribunal at the right time.” *Guinan v. United States*, 6 F.3d 468, 474 (7th Cir. 1993) (Easterbrook, J. Concurring). Mr. Patel could not have presented his claim to the Sixth Circuit as to whether his plea was knowing and voluntary, particularly when the claim must be viewed in the context of numerous instances in which trial counsel was constitutionally ineffective, and which are not evidenced in the existing trial court record.

Federal appellate courts have repeatedly criticized litigants who have attempted to expand the appellate record *ex parte*. See, e.g. *Matter of Carlson*, 126 F.3d 915 (7th Cir. 1997) (grant motion to strike from record materials attached to the appellant’s brief which were not contained in the lower court record). It would have been wholly improper for Mr. Patel to attempt to litigate this issue by *ex parte* affidavit in the Sixth Circuit. Furthermore, Fed.R.Crim.P. 11(e), actually contemplates that, after imposition of sentence a guilty plea may be set aside in a collateral attack.

On it’s face it may not appear that Mr. Patel plea was unknowing or involuntary since there was seeming compliance with the requirements of Fed.R.Crim.P. 11. However, upon a closer review of the plea record, it is clear that the requirement of

sub-paragraph (b)(3) was not satisfied in that the Court failed to recognize that the plea soliloquy by Mr. Patel failed to establish the scienter element to either offence. This deficiency was not cured by any contemporaneous offer of proof by counsel for either party nor by reference to the factual admissions contained in the written Rule 11 plea agreement. The Agreement itself also substantively misstated the elements of the charged offenses. It cannot be said that an accused has tendered a knowing plea when he was misled as the requisite *mens rea* of these offenses. While it might readily be inferred from Mr. Patel's insistence that he was unaware of the unlawful conduct of his employees, he is prepared to testify at an evidentiary hearing that he was misled as to the requisite intent necessary to sustain a conviction for the offenses to which he pled.

Another consideration undermines a finding that Mr. Patel's plea was knowing and voluntary and that is the constitutionally inadequate performance of defense counsel. Based on the deficiencies in the factual basis for the plea, as discussed above, it might be inferred that defense counsel failed to conduct even elementary investigation of the elements of the charges offenses, failed to advise his client that the conduct to which he admitted did not constitute criminal offenses, misled the client into believing that he did not have a viable defense to the charged offenses, and failed to notice that the Assistant United States Attorney had substantively misstated the elements of the offenses in the Rule 11 Plea Agreement, thereby misleading his

client to believing that one could commit the charged offenses through mere negligence.

An alternative inference is that defense counsel deliberately mislead his client. Only an evidentiary hearing will allow the Court to determine whether defense counsel's conduct was grossly negligent or deliberate. Since there is no provision for an evidentiary hearing on the claim of ineffective assistance of counsel, it is more appropriate for this matter to be taken up under 28 U.S.C.A. § 2255.

II. THE DEFENDANT IS NOT REQUIRED TO DEMONSTRATE GOOD CAUSE AND PREJUDICE WHERE THE ISSUE COULD NOT HAVE BEEN RAISED IN HIS ORIGINAL APPEAL.

Mr. Patel waived his right to take a direct appeal to the Circuit Court in his Rule 11 Plea Agreement. He did not waive his right to seek collateral review under 28 U.S.C.A. § 2255. That said, the waiver is moot since the issues raise herein are not appropriate for direct review and would need to have been brought as an action under 28 U.S.C.A. § 2255 in any case.

Mr. Patel is not required to demonstrate good cause and actual prejudicial as a prerequisite to bringing this petition. The issues presented in this motion require extra-record development. It would have been wholly inappropriate for Mr. Patel to attempt to provide the Sixth Circuit with the necessary proofs to support this petition when those proofs did not appear in the lower court record. Only by proceeding via

a 28 U.S.C.A. § 2255 petition can Mr. Patel adequately develop the record for appellate review. In accordance with the current precedent from the United States Supreme Court, he is therefore exempt from meeting the cause and prejudice test.

Ordinarily, when a person files a petition collaterally challenging his criminal conviction, that individual is required to demonstrate good cause for not raising the matter on the initial appeal and resultant prejudice. See *United States v. Frady*, 456 U.S. 152, 167-168, 102 S.Ct. 1584 (1982); *Bousley v. United States*, 523 U.S. 614, 621-622, 118 S.Ct. 1604 (1998). The United States Supreme Court, however, recently made it clear that the *Frady* principle is not applicable where a claim cannot be raised in the appeal of right. *Massaro v. United States*, 538 U.S. 500, 123 S.Ct. 1690 (2003).

In *Massaro*, the Court resolved an inter-circuit conflict on this precise issue. Prior to *Massaro*, the federal appellate courts were not in agreement when issues had to be raised in an appeal of right and when issues had to be raised in a 28 U.S.C.A. § 2255 petition. *United States v. Frady*, supra, had created what could have been read as a *per se* rule which said that any time an individual raised an issue in a Section 2255 proceeding, he or she was required to demonstrate good cause for the procedure default and actual prejudice. Other courts had held that a prisoner was excused from raising these issues only when it was impossible to raise the issue on the original appeal. See, e.g. *United States v. Phillips*, 914 F.2d 835, 846 (7th Cir.1990) ("Of course, when an appellate court is able to evaluate the grounds upon which trial

counsel is said to be ineffective on the existing record, the claim of ineffectiveness is forfeited if not initially raised on appeal.")

In *Massaro*, the Court took judicial notice that the appellate practice in the United States had evolved to the extent that challenges such as the instant one were presented for the first time in collateral proceedings. The original record of the proceedings were not designed to address these issues and a court could not adequately work from such a record:

In light of the way our system has developed, in most cases a motion brought under § 2255 is preferable to direct appeal for deciding claims of ineffective-assistance. When an ineffective-assistance claim is brought on direct appeal, appellate counsel and the court must proceed on a trial record not developed precisely for the object of litigating or preserving the claim and thus often incomplete or inadequate for this purpose. Under *Strickland v. Washington*, 466 U.S. 668, 104 S.Ct. 2052, 80 L.Ed.2d 674 (1984), a defendant claiming ineffective counsel must show that counsel's actions were not supported by a reasonable strategy and that the error was prejudicial. The evidence introduced at trial, however, will be devoted to issues of guilt or innocence, and the resulting record in many cases will not disclose the facts necessary to decide either prong of the *Strickland* analysis. If the alleged error is one of commission, the record may reflect the action taken by counsel but not the reasons for it. The appellate court may have no way of knowing whether a seemingly unusual or misguided action by counsel had a sound strategic motive or was taken because the counsel's alternatives were even worse. See *Guinan*, supra, at 473 (Easterbrook, J., concurring) ("No matter how odd or deficient trial counsel's performance may seem, that lawyer may have had a reason for acting as he did Or it may turn out that counsel's overall performance was sufficient despite a glaring omission ..."). The trial record may contain no evidence of alleged errors of omission, much less the reasons underlying them. And evidence of alleged conflicts of interest might be found only in attorney-client correspondence or other documents that, in the typical criminal trial, are not introduced. See, e.g.,

Billy-Eko, 8 F.3d, at 114. Without additional factual development, moreover, an appellate court may not be able to ascertain whether the alleged error was prejudicial.

Id at 1694.

Based on this, Justice Kennedy writing for a unanimous court, concluded that the most efficient manner for a case to proceed was for all such challenges to be raised in the collateral 28 U.S.C.A. § 2255:

Under the rule we adopt today, ineffective-assistance claims ordinarily will be litigated in the first instance in the district court, the forum best suited to developing the facts necessary to determining the adequacy of representation during an entire trial. The court may take testimony from witnesses for the defendant and the prosecution and from the counsel alleged to have rendered the deficient performance. See, *e.g.*, *Griffin*, *supra*, at 1109 (In a § 2255 proceeding, the defendant "has a full opportunity to prove facts establishing ineffectiveness of counsel, the government has a full opportunity to present evidence to the contrary, the district court hears spoken words we can see only in print and sees expressions we will never see, and a factual record bearing precisely on the issue is created"); *Beaulieu v. United States*, 930 F.2d 805 (C.A.10 1991) (partially rev'd on other grounds *United States v. Galloway*, *supra*). In addition, the § 2255 motion often will be ruled upon by the same district judge who presided at trial. The judge, having observed the earlier trial, should have an advantageous perspective for determining the effectiveness of counsel's conduct and whether any deficiencies were prejudicial.

The former approach followed by some circuits introduced inefficiencies into the process. It created a premature war between defense counsel and appellate counsel, and forced original appellate counsel to mount challenges which they knew could not be supported by the record. *Id.*

III. DEFENDANT’S PLEA WAS FATALLY DEFECTIVE BECAUSE THERE WAS NO FACTUAL BASIS FOR THE FINDING OF THE REQUISITE SCIENTER FOR THE OFFENSES TO WHICH HE PLED.

Fed.R.Crim.P. 11(b)(1)(G) requires, among other things, that before the court accepts a defendant’s guilty plea the court “must inform the defendant of, and determine that the defendant understands ... the nature of each charge to which the defendant is pleading.]” *United States v. Moore*, 423 Fed.Appx. 495 (6th Cir. 2011) The “district court must be satisfied, after discussion with the defendant in open court, that the defendant understands the elements of the offense.” *United States v. McCreary–Redd*, 475 F.3d at 723 (6th Cir. 2007)(citations omitted).

Fed.R.Crim.P. 11(b)((3) requires that the court must determine that there is a factual basis for the plea prior to entering a judgment of guilt. The judge must examine the accused to determine that the conduct to which the defendant admits embraces all of the elements of the offense. Requiring this examination of the relation between the law and the acts the defendant admits having committed is designed to “protect a defendant who is in the position of pleading voluntarily with an understanding of the nature of the charge but without realizing that his conduct does not actually fall within the charge.” *McCarthy v. United States*, 394 U.S. 459 at 467, 89 S.Ct. at 1171 (footnote omitted). In accord, *United States v. Goldberg*, 862 F.2d

101(6th Cir. 1988); *United States v. Wahl*, 991 F.2d 797 (6th Cir. 1993); *United States v. Tunning*, 69 F.3d 107 (6th Cir. 1995).

Although Rule 11(h) provides a harmless error provision for certain deviations from the Rule, the failure to secure an adequate factual basis is a substantial defect which undermines the validity of the plea. Failure to establish an adequate factual basis is never harmless error. *United States v. Luce*, 713 F.2d 1236 (6th Cir. 1983); *United States v. Van Buren*, 804 F.2d 888 (6th Cir. 1986); *United States v. Goldberg*, supra; *United States v. Tunning*, supra; *United States v. Williams*, 176 F.3d 301(6th Cir. 1999); *United States v. McCreary–Redd*, supra.

While it will require some repetition, for the sake of clarity, the elements of each offense and the proffered factual basis for each offense will be discussed separately.

Plea to 21 U.S.C.A. § 842(a)

21 U.S.C.A. § 842(a), unlawful distribution of a controlled substance, under which Mr. Patel was charged, provides that:

(a) Unlawful acts

It shall be unlawful for any person--

- (1) who is subject to the requirements of part C to distribute or dispense a controlled substance in violation of section 829 of this title;

The penalty for the, if charged in an information or indictment, is governed by 21 U.S.C.A. § 842(c)(2)(A), which provides:

If a violation of this section is prosecuted by an information or indictment which alleges that the violation was committed knowingly and the trier of fact specifically finds that the violation was so committed, such person shall, except as otherwise provided in subparagraph (B) of this paragraph, be sentenced to imprisonment of not more than one year or a fine under Title 18, or both.

If there is no specific finding that the violation was committed knowingly then the violation is treated only as a civil offense and the penalty for the violation would be governed by 21 U.S.C.A. § 842(c)(1)(A), which provides:

Except as provided in subparagraph (B), (C), or (D) of this paragraph and paragraph (2), any person who violates this section shall, with respect to any such violation, be subject to a civil penalty of not more than \$25,000. The district courts of the United States (or, where there is no such court in the case of any territory or possession of the United States, then the court in such territory or possession having the jurisdiction of a district court of the United States in cases arising under the Constitution and laws of the United States) shall have jurisdiction in accordance with section 1355 of Title 28 to enforce this paragraph.

21 U.S.C.A. § 829, referred to above, which governs prescriptions, provides in relevant part¹ that:

(b) Schedule III and IV substances

Except when dispensed directly by a practitioner, other than a pharmacist, to an ultimate user, no controlled substance in schedule III or IV, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, may be dispensed without a written or

¹ It is undisputed that the drug in question, Ketamine, is a Schedule III drug.

oral prescription in conformity with section 503(b) of that Act. Such prescriptions may not be filled or refilled more than six months after the date thereof or be refilled more than five times after the date of the prescription unless renewed by the practitioner.

Factual Basis in Rule 11 Agreement

The parties Rule 11 Plea Agreement, recited the factual basis for Mr. Patel's plea to the unlawful distribution of a controlled substance. Those facts pertinent only to the healthcare fraud count have been redacted.

Deven Patel was the was the [sic] beneficial owner of Southfield Medical Pharmacy and as such **was responsible to assure** that the Pharmacy's operations were in compliance with federal and state laws and regulations, **to assure** that controlled substances at Southfield Medical Pharmacy were dispensed only pursuant to a valid prescription * * * * . Section 842(a)(1) of the Controlled Substances Act (CSA) provides that it is unlawful for any person to distribute or dispense a controlled substance for a Sechedule III controlled substance without a written or oral prescription, * * * * During the period of October, 2009 through June 2010, **Deven Patel with indifference to his obligation under the CSA**, allowed Southfield Medical Pharmacy to dispense a specialty compound topical cream know as A1 Topical Cream which contained ketamine, a Schedule 3 controlled substance, **without first obtaining a valid written or oral prescription from Dr. Mendiratta's medical office in violation of 21 USC 842(a)(1)**, * * * *. [emphasis in the original]

Factual Basis at Plea

At the time of the plea, Mr. Patel was asked the Court to explain what he did.

Mr. Patel said:

Your Honor, I failed to supervise certain employees under my control and direct supervision and said employees unlawfully distributed and/or dispensed a Schedule III controlled substance known as Compounding

Topical Creme, also know as A1 Topical Creme which contained Ketamine . . . and this is without a valid supervision. Specifically during the period of October, 2009 through June, 2010 certain pharmacist working for me at the Southfield Medical Pharmacy dispensed A1 Topical Creme, a Schedule III controlled substance without a valid prescription. As the owner and manager of these individuals, I should have known of this unlawful activity. For these reasons I enter this plea and accept responsibility for my actions.

[Plea Transcript, p. 13]

There were no follow-up questions about the scope of Mr. Patel's knowledge or involvement in the dispensation of the controlled substance by the Court, the Assistant United States Attorney or defense counsel, nor were there any supplemental proffers of proof as to the element of scienter. The Court made no specific finding as to Mr. Patel's knowledge as is required under 21 U.S.C.A. § 842(c)(2)(A). (Plea Transcript, p. 14 and again at 15)

As these records make perfectly clear, certain pharmacists employed by Mr. Patel unlawfully dispensed a controlled substance and did so without Mr. Patel's knowledge or participation. Mr. Patel, in his plea, admits to negligently supervising the pharmacists who worked for him who did these unlawful acts. Nothing in either the Rule 11 Agreement or in the plea colloquy support even the slightest inference that the unlawful distribution was done with his knowledge or consent. He says "I should have known about this unlawful activity". He tells the Court, under oath, that he did not know what was going on behind his back. For a violation of 21 U.S.C.A.

§ 842(a) to constitute a crime, rather than a civil infraction, there must be a factual basis for finding the requisite scienter of “knowingly” and not mere negligence.

The United States Supreme Court has defined what “knowing” means in the context of a federal statute. It means knowledge of the facts which constitute the offense. *Dixon v. United States*, 548 U.S. 1126 S.Ct. 2437 (2006); *Bryan v. United States* 524 U.S. 184, 193, 118 S.Ct. 1939 (1998). In accord in this Circuit, see *United States v. Honeycutt*, 816 F.3d 362 (6th Cir. 2016). The single fact which made the dispensation of a controlled substance by Mr. Patel’s employees an offense was the fact that the prescriptions were not valid.

It should be noted that in the vast majority of cases in which the adequacy of the factual basis is at issue, there was an issue as to the omission of facts to support a finding of an element of the offense. In this case, it is not the absence of facts supporting the requisite scienter element but the fact that in both the Rule 11 proffer and during the plea colloquy, Mr. Patel clearly and repeatedly denied that he acted knowingly and made clear that his culpability rested solely on his admission of negligent oversight of fellow professional pharmacists.

Lest the Court draw the erroneous inference that there was something in the nature of this topical crime which should have made it subject to a heightened level of scrutiny by Mr. Patel, several facts about this preparation must be recognized. Ketamine is used by medical practitioners and veterinarians as an anaesthetic. It is

sometimes used illegally by people to get 'high'. Ketamine can produce hallucinogenic effects, causing a person to see, hear, smell, feel or taste things that aren't really there or are different from how they are in reality. When it's sold illegally, ketamine usually comes as a white crystalline powder. It can also be made into tablets and pills, or dissolved in a liquid.²

Ketamine creme, on the other hand, has virtually no prospect of recreational abuse. It cannot be smoked, ingested, injected or inhaled. There is no practical method to extract the Ketamine from the creme base. Ketamine creme is used for management of chronic neuropathic pain and complex regional pain syndrome. It has no euphoric effect; it merely reduces the sensitivity of the patch of skin to which is applied. It is devoid of serious side-effect.³ There would be no reason to carefully scrutinize prescriptions for Compounding Topical Creme.

It should also be kept in mind that Southfield Medical Pharmacy is a compounding pharmacy. The vast majority of pharmacies are merely dispensaries. They simply dole out drugs prescribed by a doctor which have been manufactured by a pharmaceutical company. Compounding pharmacies actually fabricate the drugs that a doctor has ordered. Most pharmacies would be unable to fill a prescription for

² Drug Enforcement Administration. (n.d.). Ketamine [PDF:580KB] [Fact sheet].

³ Analgesic effects of topical ketamine, Kopsky, et al, *Minerva Anesthesiol.* 2015 Apr; 81(4):440-9.

Compounding Topical Creme. This means that prescriptions such as these will be funnelled to the few pharmacies which can fabricate the compound. Further, given the therapeutic use for the drug, it would most often be prescribed by a small number of doctors who specialize in the management of chronic pain. It is a prudent method used to treat people with certain types of chronic pain, since it avoids the use of habit-forming and debilitating narcotic drugs. This Court also must remember that the pharmacy in question was directly across the patient waiting area from the doctor's office. A reasonably prudent pharmacist may rely on the knowledge that they have developed from a close working relationship with the doctor's office which would include things like familiarity with signatures, office practices, etc.

Thus, neither the number of prescriptions for the creme nor the fact that the prescriptions were written by a limited number of physicians, would have given rise to any concerns by an experienced compounding pharmacist. A knowledgeable pharmacist would recognize that the prescriber has made a conscious decision to avoid the use of narcotic drugs to treat the patient's pain.

Plea to 18 U.S.C.A. §1347

18 U.S.C.A. §1347, healthcare fraud, under which Mr. Patel was charged, provides that:

(a) Whoever knowingly and willfully executes, or attempts to execute, a scheme or artifice –

(1) to defraud any health care benefit program; or

(2) to obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any health care benefit program, in connection with the delivery of or payment for health care benefits, items, or services, shall be fined under this title or imprisoned not more than 10 years, or both. If the violation results in serious bodily injury (as defined in section 1365 of this title), such person shall be fined under this title or imprisoned not more than 20 years, or both; and if the violation results in death, such person shall be fined under this title, or imprisoned for any term of years or for life, or both.

(b) With respect to violations of this section, a person need not have actual knowledge of this section or specific intent to commit a violation of this section.

Factual Basis in Rule 11 Agreement

The parties Rule 11 Plea Agreement, recited the factual basis for Mr. Patel's plea to healthcare fraud. There has been no redaction; Mr. Patel's lack of knowledge as to the invalidity of the prescriptions is relevant to this count as well.

Deven Patel was the was the [sic] beneficial owner of Southfield Medical Pharmacy and as such was responsible to assure that the Pharmacy's operations were in compliance with federal and state laws and regulations, to assure that controlled substances at Southfield Medical Pharmacy were dispensed only pursuant to a valid prescription, and to assure that claims submitted to private insurers for reimbursement were only for medications that were lawfully prescribed. Section 842(a)(1) of the Controlled Substances Act (CSA) provides that it is unlawful for any person to distribute or dispense a controlled substance for a Sechedule III controlled substance without a written or oral prescription, In addition, 18 USC 1347(a)(1) provides that it is unlawful to defraud any health care benefit program in connection with the delivery of or

payment for health care benefits, items, or services. During the period of October, 2009 through June 2010, Deven Patel with indifference to his obligation under the CSA, allowed Southfield Medical Pharmacy to dispense a specialty compound topical cream know as A1 Topical Cream which contained ketamine, a Schedule 3 controlled substance, without first obtaining a valid written or oral prescription from Dr. Mendiratta's medical office in violation of 21 USC 842(a)(1), and allowed Southfield Medical Pharmacy to beill and to receive reimbursement for these prescription medications from health care benefits programs, including Blue Cross, Medco and CV/Caremark, in violation of 18 USC 1347.

Factual Basis at Plea

At the time of the plea, Mr. Patel was asked the Court to explain what he did.

Mr. Patel said:

PATEL: Your Honor, I failed to supervise certain employees under my control and direct supervision and said employees unlawfully distributed and/or dispensed a Schedule III controlled substance known as Compounding Topical Creme, also known as AI Topical Creme which contained Ketamine, K-e-t-a-m-i-n-e, which contained Ketamine [sic] and this is without a valid prescription. Specifically during the period of October, 2009 through June, 2010 certain pharmacists working for me at the Southfield Medical Pharmacy dispensed AI Topical Creme, a Schedule III controlled substance without a valid prescription. As the owner and manager of these individuals, I should have known of this unlawful activity. For these reasons I enter this plea and accept responsibility for my actions.

THE COURT: And, Mr. Patel, did you have any -- were there bills submitted in connection with filling of these unlawful prescriptions?

MR. PATEL: Yes, Your Honor.

THE COURT: And where were they submitted?

MR. PATEL: They were submitted for reimbursement for -- through health care benefit programs such as Blue Cross, Medco and CVS.

THE COURT: And what pharmacy did this activity occur?

MR. PATEL: Southfield Medical Pharmacy.

THE COURT: Where is that located?

MR. PATEL: At 26699 West 12 Mile in Southfield, Ste 200.

THE COURT: Mr. Soisson, do you have questions?

MR. SOISSON: No, Your Honor. Thank you.

THE COURT: And Counsel, Mr. Crandall, Mr. Cassar, do you have questions?

MR. CRANDALL: I would just point out that is in the Eastern District of Michigan, Your Honor.

THE COURT: Yes. Counsel, are you satisfied Mr. Patel has made out the elements of these two charges of Health Care Fraud and Distribution of Controlled Substance?

MR. CRANDALL: He's really just on Count One so far, Your Honor.

THE COURT: He's just on Count One? All right. Do you want to say more?

MR. PATEL: On Count Two it's as stated above, during the period October, 2009 through June, 2010 certain pharmacists working for me at the Southfield Medical Pharmacy dispensed AI Topical Creme, a Schedule III controlled substance without valid a prescriptions. As owner/manager of the business and supervisor of the employees, I allowed Southfield Medical Pharmacy to bill and receive reimbursement for these prescription medications from health care benefit programs, including Blue Cross, Medco and CVS.

THE COURT: So satisfied on Count Two as well?

MR. SOISSON: Yes.

MR. CRANDALL: Yes, Your Honor.

THE COURT: Thank you. The Court believes that Mr. Patel has made out the elements of the crimes charged in both Counts One and Two, Health Care Fraud and Distribution of Controlled Substance. [Plea Transcript, pp. 13-15]

There were no further follow-up questions about the scope of Mr. Patel's knowledge or involvement in the dispensation of the controlled substance or his role in billing health care providers by the Court, the Assistant United States Attorney or defense counsel, nor were there any supplemental proffers of proof as to the element of scienter on either count. (Plea Transcript, *passim*)

As these records make perfectly clear, certain pharmacists employed by Mr. Patel unlawfully dispensed a controlled substance and did so without Mr. Patel's knowledge or participation. Mr. Patel, in his plea, admits to negligently supervising the pharmacists who worked for him who did these unlawful acts. Nothing in either the Rule 11 Agreement or in the plea colloquy support even the slightest inference that the unlawful distribution was done with his knowledge or consent. He says "I should have known about this unlawful activity". He tells the Court, under oath, that he did not know what was going on behind his back.

Given that Mr. Patel is clear in both the Rule 11 proffer and in his plea colloquy that he did not know that the prescriptions for the creme were invalid, he would have

no reason whatsoever to instruct his employees who handled billings not to bill the various health care providers for reimbursement.

In *United States v. White*, 492 F.3d 380, 393 (6th Cir. 2007) the Sixth Circuit enunciated what the elements are in a prosecution for healthcare fraud under 18 U.S.C.A. § 1347:

To sustain a Medicare fraud conviction under § 1347, the government must prove that the defendant “(1) knowingly devised a scheme or artifice to defraud [Medicare] in connection with the delivery of or payment for [Medicare] benefits, items, or services; (2) executed or attempted to execute this scheme or artifice to defraud; and (3) acted with intent to defraud.” *United States v. Raithatha*, 385 F.3d 1013, 1021 (6th Cir.2004), judgment vacated on other grounds, 543 U.S. 1136, 125 S.Ct. 1348, 161 L.Ed.2d 94 (2005). Thus, the government must prove the defendant's “specific intent to deceive or defraud.” *United States v. Frost*, 125 F.3d 346, 354 (6th Cir.1997).

To convict a person under 18 U.S.C.A. § 1347, there must be facts which show that the person knowingly and willingly engaged in a scheme to defraud a healthcare provider. To constitute a crime there must be a factual basis for finding the requisite scienter of “knowingly” and “willingly”; it must show that the accused knew that it was a scheme to defraud and knowing that it was fraudulent, actually participated in the scheme. A conviction cannot rest mere negligent oversight or a failure to detect deliberately secreted behavior by an employee.

The United States Supreme Court has defined what “knowing” means in the context of a federal statute. It means knowledge of the facts which constitute the

offense. *Dixon v. United States*, 548 U.S. 1, 5; 126 S.Ct. 2437 (2006); *Bryan v. United States* 524 U.S. 184, 193; 118 S.Ct. 1939 (1998). In accord in this Circuit, see *United States v. Honeycutt*, 816 F.3d 362 (6th Cir. 2016). The term “willfully” requires a defendant to have “acted with knowledge that his conduct was unlawful.” *Ibid*.

The Sixth Circuit pattern jury instruction 6thCirPJI Criminal 10.05 sheds some additional light on the *mens rea* required for a conviction under 18 U.S.C.A. § 1347:

. . . scheme to defraud includes any plan or course of action by which someone intends to deprive another of money or property by means of false or fraudulent pretenses, representations, or promises. . . .

. . . An act is done knowingly and willfully if it is done voluntarily and intentionally and not because of mistake or some other innocent reason.
. . .

An act with intent to defraud means to act with intent to deceive or cheat for the purpose of either causing a financial loss to another or bringing about a financial gain to oneself.

The single fact which made the reimbursement claims to the healthcare providers unlawful was the fact offense was the fact that the prescriptions were not valid. In the absence of facts showing that Mr. Patel knew that the prescriptions were invalid, and in the face of his assertions that he was ignorant of that fact, there is no basis for finding that the submission of routine reimbursement requests to healthcare providers by Mr. Patel’s bookkeeping staff was done with the intent to defraud and there is no factual basis for finding that he acted knowingly and willingly and not out of a mistaken belief that the reimbursement requests were normal and proper.

The failure to establish the proper scienter element of either offense is fatal. As the Sixth Circuit noted in *U.S. v. Tunning*, 69 F.3d 107 (6th Cir. 1995):

In *McCarthy v. United States*, 394 U.S. 459, 89 S.Ct. 1166, 22 L.Ed.2d 418 (1969), the Supreme Court adopted a rule of strict compliance with the procedures of Rule 11. This rule was modified in 1983 with the adoption of Rule 11(h), which provides that variations from the requirements of Rule 11 are excusable so long as they do not affect the “substantial rights” of the defendant. See, e.g., *United States v. Goldberg*, 862 F.2d 101 (6th Cir.1988). However, this “harmless error” analysis does not apply to appellate review of the sufficiency of the factual basis supporting the guilty plea. “ ‘[W]hile the exact method of producing a factual basis on the record is subject to a flexible standard of review, the need to have some factual basis will continue to be a rule subject to no exceptions.’ ” Id. at 106 (quoting *United States v. Fountain*, 777 F.2d 351, 357 (7th Cir.1985), cert. denied, 475 U.S. 1029, 106 S.Ct. 1232, 89 L.Ed.2d 341 (1986)).

Conclusion

For the reasons set forth above, both of Mr. Patel’s pleas fail because there is no factual basis in the record for finding the proper required *mens rea* for either offense. They must be set aside.

IV. THE DEFENDANT WAS DENIED EFFECTIVE ASSISTANCE OF COUNSEL WHEN COUNSEL'S ERRONEOUS LEGAL ADVICE AS TO SCIENTER INDUCED HIM TO PLEAD GUILTY FOR CONDUCT WHICH IS NOT IN FACT CRIMINAL AND RENDERED HIS PLEAS UNKNOWNING AND INVOLUNTARY.

Presuming that counsel's erroneous legal advice was not deliberate, counsel's original sin was his failure to properly conduct legal research as to the intent element of the charged offenses. This initial omission gave rise to a series of errors. Counsel failed to factually investigate a viable state of mind defense and failed to interview witnesses that would have supported the defense. It also resulted in counsel giving Mr. Patel erroneous legal advice as to whether the criminal charges were potentially defensible and whether or not it was advisable to enter into a plea agreement with the government. It continued when he approved the Rule 11 Plea Agreement which substantively misstated the elements of the charged offenses, including the *mens rea* element of each offense and advised Mr. Patel to accept the agreement. This series of errors crystalized in a plea whose factual admissions failed to satisfy the intent element of either of the charged offenses. Mr. Patel pled to conduct which does not constitute a crime. Mislead by counsel's advice, his plea was neither knowing nor voluntary.

A guilty plea is voluntary relinquishment of all the rights associated with a trial. In order for such a plea to be valid, a court is required to determine that the plea was

voluntarily and knowingly tendered. *Brady v. United States*, 397 U.S., at 756--757, 90 S.Ct., at 1473--1474 (1970); *Boykin v. Alabama*, 395 U.S. 238, 242, 89 S.Ct. 1709, 1711--1712 (1969). While guilty pleas are common place, it is vital that the court remain sensitive to the serious implications of such a plea. As Justice White recognize in *Brady*:

That a guilty plea is a grave and solemn act to be accepted only with care and discernment has long been recognized. Central to the plea and the foundation for entering judgment against the defendant is the defendant's admission in open court that he committed the acts charged in the indictment. He thus stands as a witness against himself and he is shielded by the Fifth Amendment from being compelled to do so-- hence the minimum requirement that his plea be the voluntary expression of his own choice. But the plea is more than an admission of past conduct; it is the defendant's consent that judgment of conviction may be entered without a trial--a waiver of his right to trial before a jury or a judge. Waivers of constitutional rights not only must be voluntary but must be knowing, intelligent acts done with sufficient awareness of the relevant circumstances and likely consequences.

Id at 748 (footnote omitted). Under *Brady* and the cases that follow it, this Court must examine the totality of the circumstances surrounding that plea. *Henderson v. Morgan*, 426 U.S. 637, 644-45, 96 S.Ct. 2253 (1976). The touchstone of such an inquiry is whether the "accused understand[s] the nature of the constitutional protections that he is waiving" and whether his admission can stand as "an intelligent admission of guilt." *Id.* at 645, n. 13.

The Federal Rules of Criminal Procedure partially implement this design by requiring a direct interrogation of the accused concerning his involvement. See gen.

Fed.R.Crim.P. 11. Mr. Patel does not dispute that this Court fully complied with the Rule as to Mr. Patel's waiver of rights. The problem arises in that he voluntarily waived his trial rights in a mistaken belief that negligent supervision of his employees was felonious. He made that mistake by relying on the erroneous advice of defense counsel who told him that the conduct to which he admitted was criminal. The plea certainly was not intelligently made, since it rested on a misapprehension of the law. It wasn't as if he didn't understand his lawyer's legal advice, the problem was that the advice was objectively wrong. His own attorney's erroneous advice was re-enforced by the United States Attorney concurrence in the mis-statement of the law.

Facial compliance to the requirements of the Rule does not render the pleas voluntary; federal case law is replete with examples where a plea was involuntary based on facts not appearing within the four corners of a guilty plea transcript. For example, a plea is invalid if counsel's performance fell below an objective standard of reasonableness and whether there is a reasonable probability that but for counsel's errors the defendant would not have pleaded guilty. *Hill v Lockhart*, 474 US 52, 106 S Ct 366 (1985); *McMann v Richardson*, 397 US 759, 90 S.Ct. 1441(1970); *Tollett v Henderson*, 411 US 258, 93 S.Ct. 1602 (1973). A plea which is either involuntary or unintelligent must be vacated. *Lefkowitz v. Newsome*, 420 US 283, 95 S Ct 886 (1975).

In *McDonald v Burke*, 149 F.3d 1183 (6th Cir. 1998) (table decision), the Sixth Circuit recognized that a guilty plea can be collaterally attacked on the theory that it was induced by improper pressure or erroneous legal advice from defense counsel. The Court held:

It has long been settled that "[a] guilty plea is open to attack on the ground that counsel did not provide the defendant with 'reasonably competent advice.'" ' *Cuyler v. Sullivan*, 446 U.S. 335, 344, 100 S.Ct. 1708, 64 L.Ed.2d 333 (1980) (quoting *McMann v. Richardson*, 397 U.S. 759, 770-71, 90 S.Ct. 1441, 25 L.Ed.2d 763 (1970)). In the guilty-plea context, the Supreme Court employs the same two-part standard for ineffectiveness that was developed in *Strickland v. Washington*, 466 U.S. 668, 104 S.Ct. 2052, 80 L.Ed.2d 674 (1984). See *Hill v. Lockhart*, 474 U.S. 52, 58, 106 S.Ct. 366, 88 L.Ed.2d 203 (1985). That is, a defendant must demonstrate that (1) his attorney's performance was outside the range of competence demanded of attorneys in the criminal context, and (2) the professionally unreasonable performance prejudiced him.

Id at **6.

The first prong of *Strickland*, requires that Mr. Patel's attorney's performance was outside of the range of competence demanded of attorneys in the criminal context. One might infer that trial counsel failed to even read the statutes under which Mr. Patel was charged. As set forth above in the first issue, the words "knowingly" and "willfully" appear in the text of the statute and in neither statute is there and mention of negligent supervision. Although in a few criminal statutes, the *mens rea* element must be inferred, in both statutes it is explicit. Reading the statute would have informed defense counsel that more than mere negligence needed to be

shown in order to support a conviction. A reasonably competent attorney would have focused immediately on the scienter problem given that the government was not alleging that Mr. Patel actually committed any overt act and the government had not charged a conspiracy. It's rather easy to infer incompetence based on the content of the Rule 11 plea agreement and the plea proceedings but an evidentiary hearing will allow the a more detailed development of the record.

As to the second prong of *Strickland*, Mr. Patel must show prejudice. Pleading guilty to conduct which is not criminal and being sent to prison as a result is unarguably rather prejudicial. This was not a sweetheart plea agreement. Mr. Patel pled guilty to both charged offenses. No charges were dismisses; no charges were reduced; no below guidelines sentence was stipulated. Mr. Patel gained nothing from the agreement that he could not have obtained by simply pleading guilty without an agreement.

RELIEF REQUESTED

WHEREFORE, Mr. Patel request that this Court vacate his pleas and schedule this matter for trial.

Respectfully submitted,

/s/Stuart G. Friedman

STUART G. FRIEDMAN (P46039

Attorney for Defendant

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DATED: November 21, 2016

CERTIFICATE OF SERVICE

The United States Attorney's Office was this 21st day of November, 2016 served with a copy of this Petition via the Court's ECF filing system.

Respectfully submitted,

/s/Stuart G. Friedman

STUART G. FRIEDMAN (P46039)

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DATED: November 21, 2016